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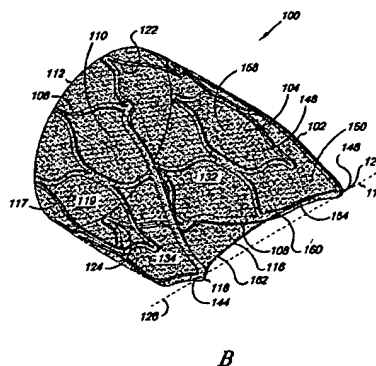
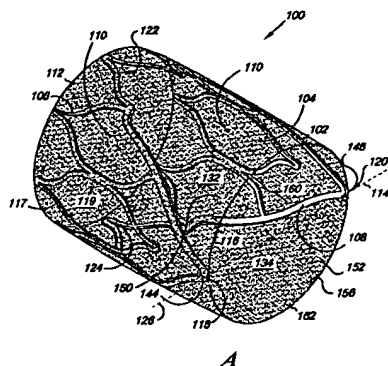
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(54) Title: **VENOUS VALVE APPARATUS, SYSTEM, AND METHOD**



(57) Abstract: A venous valve (100) with a tubular frame (102) that includes an outer surface and an inner surface opposite the outer surface and defining a lumen, and a cover (104) over at least the outer surface of the tubular frame, where the cover includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid through the lumen. A system with the venous valve and a catheter including a proximal end and a distal end, the venous valve located between the proximal end and distal end of the catheter. A method including forming the venous valve and reversibly joining the venous valve and a catheter.

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Venous Valve Apparatus, System, and Method

Field of the Invention

The present invention relates generally to apparatus, systems, and methods for use in a lumen; and more particularly to venous valve apparatus, systems, and methods for use in the vasculature system.

Background of the Invention

The venous system of the legs uses pumps and valves to return blood to the heart. Venous valves create one way flow to prevent blood from flowing away from the heart. When valves fail, blood can pool in the lower legs resulting in swelling and ulcers of the leg. The absence of functioning venous valves can lead to chronic venous insufficiency.

Techniques for both repairing and replacing the valves exist, but are tedious and require invasive surgical procedures. Direct and indirect valvuoplasty procedures are used to repair damaged valves. Transposition and transplantation are used to replace an incompetent valve. Transposition involves moving a vein with an incompetent valve to a site with a competent valve. Transplantation replaces an incompetent valve with a harvested valve from another venous site. Prosthetic valves can be transplanted into the venous system, but current devices are not successful enough to see widespread usage.

Brief Description of the Drawings

Figures 1A and 1B illustrate an embodiment of a valve.

Figures 2A-2D illustrate an embodiment of a valve in perspective view (Figure 2A and 2B) and sectional view (Figure 2C and 2D) of the valve.

Figures 3A and 3B illustrate an embodiment of a valve in a compressed state (Figure 3A) and in an expanded state (Figure 3B).

Figures 4A-4D illustrate an embodiment of forming a valve.

Figures 5A-5C illustrate an embodiment of forming a cover.

Figures 6A-4E illustrate an embodiment of forming a valve.

Figures 7A-7D illustrate an embodiment of forming a valve.

Figure 8 illustrates an embodiment of a system that includes a valve.

Figure 9 illustrates an embodiment of a system that includes a valve.

Figure 10 illustrates an embodiment of a system that includes a valve.

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Detailed Description

Embodiments of the present invention are directed to an apparatus, system, and method for valve replacement. For example, the apparatus can include a valve that can be used to replace an incompetent valve in a body lumen. Embodiments of the valve can include a tubular frame and cover that can be implanted through minimally-invasive techniques into the body lumen. In one example, embodiments of the apparatus, system, and method for valve replacement may help to maintain antegrade blood flow, while decreasing retrograde blood flow in a venous system of individuals having venous insufficiency, such as venous insufficiency in the legs.

15 The Figures herein follow a numbering convention in which the first digit or digits correspond to the drawing Figure number and the remaining digits identify an element or component in the drawing. Similar elements or components between different Figures may be identified by the use of similar digits. For example, 110 may reference element "10" in Figure 1, and a similar element may be referenced as 210 in Figure 2. As will be appreciated, elements shown in the various embodiments herein can be added, exchanged, and/or eliminated so as to provide any number of additional embodiments of valve.

25 Figures 1A-3 provide illustrations of various embodiments of a valve of the present invention. Generally, valve can be implanted within the fluid passageway of a body lumen, such as for replacement of a valve structure within the body lumen (e.g., a venous valve), to regulate the flow of a bodily fluid through the body lumen in a single direction. Figures 1A and 1B illustrate one embodiment of a venous valve 100. Venous valve 100 includes a tubular frame 102 and a cover 104 for the venous valve 100, where both the tubular frame 102 and the cover 104 can resiliently radially collapse and expand. The tubular frame 102 includes an outer surface 106 and an inner surface 108 opposite the outer surface 106. The inner surface 108 defines a

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lumen 110 of the venous valve 100 for passing fluid (e.g., blood) therethrough. The tubular frame 102 also includes a first end 112 and a second end 114.

In one embodiment, the cover 104 can be located over at least the outer surface 106 of the tubular frame 102. For example, the cover 104 can extend around a perimeter of the tubular frame 102 so as to completely cover the outer surface of the tubular frame 102. In other words, the cover 104 extends over the outer surface of the tubular frame 102 so that there are no exposed portions of the outer surface of the tubular frame 102. In an additional embodiment, the cover 104 can also be located over at least the inner surface 108 of the tubular frame 102. A further embodiment includes the cover 104 located over at least the outer surface 106 and the inner surface 108. The cover 104 can further include surfaces defining a reversibly sealable opening 116 for unidirectional flow of a liquid through the lumen 110. For example, the surfaces of the cover 104 can be deflectable between a closed configuration in which fluid flow through the lumen 110 can be restricted and an open configuration in which fluid flow through the lumen 110 can be permitted.

The tubular frame 102 can be formed from a wide variety of materials and in a wide variety of configurations. Generally, tubular frame 102 can have a unitary structure with an open frame configuration. For example, the open frame configuration can include frame members 117 that define openings 119 through the tubular frame 102. The tubular frame 102 can also be self-expanding. Examples of self-expanding frames include those formed from temperature-sensitive memory alloy which changes shape at a designated temperature or temperature range. Alternatively, the self-expanding frames can include those having a spring-bias. In addition, the tubular frame 102 can have a configuration that allows the frame 102 be radially expandable through the use of a balloon catheter.

In one embodiment, the tubular frame 102 can include an open frame configuration that includes a first vertex 118 and a second vertex 120 relative the first end 112 of the tubular frame 102. Tubular frame 102 can further include a first valley 122 and a second valley 124 adjacent the first end 112 relative the first vertex 118 and the second vertex 120. As illustrated in Figures 1A and 1B, the first vertex 118 and the second vertex 120 can be positioned opposite each other along a common axis 126. Figures 1A and 1B also illustrate that the first valley 122 and the second valley 124 can be positioned opposite each other and perpendicular to axis 126. Other

relative positions for the first and second vertex 118 and 120, and the first and second valley 122 and 124 are also possible.

Figures 2A-2D illustrate an additional embodiment of a venous valve 200. Figures 2A and 2B provide a perspective illustration of valve 200 in an open configuration (Figure 2A) and a closed configuration (Figure 2B). Figures 2C and 2D provide a sectional view of Figures 2A and 2B, respectively, to more clearly illustrate the embodiment of the venous valve 200.

Venous valve 200 includes a tubular frame 202 and a cover 204 for the venous valve 200 where both the tubular frame 202 and the cover 204 can resiliently radially collapse and expand. The tubular frame 202 includes an outer surface 206 and an inner surface 208 opposite the outer surface 206. The inner surface 208 defines a lumen 210 of the venous valve 200 for passing fluid (e.g., blood) therethrough. The tubular frame 202 also includes a first end 212 and a second end 214.

In one embodiment, the cover 204 can be located over at least the outer surface 206 of the tubular frame 202. In an additional embodiment, the cover 204 can be located over at least the inner surface 208 of the tubular frame 202. A further embodiment includes the cover 204 located over at least the outer surface 206 and the inner surface 208. The cover 204 further includes surfaces defining a reversibly sealable opening 216 for unidirectional flow of a liquid through the lumen 210. For example, the surfaces of the cover 204 can be deflectable between a closed configuration in which fluid flow through the lumen 210 can be restricted and an open configuration in which fluid flow through the lumen 210 can be permitted.

Generally, tubular frame 202 can have a unitary structure with an open frame configuration. For example, the open frame configuration can include frame members 217 that define openings 219 through the tubular frame 202. The tubular frame 202 can include an open frame configuration in which the first end 212 and the second end 214 each include a plurality of end portions 221 that lay on a common plane 223. As illustrated in Figures 2A-2D, the plurality of end portions 221 that lay on the common plane 223. However, the plurality of end portions 221 need not all lay on the common plane 223 and 222. It is possible that one or more of the end portions 221 lay above and/or below the common plane 223.

While the tubular frame 102 and/or 202 illustrated herein is shown having a circular configuration, other configurations are also possible. For example, the

tubular frame 102 and/or 202 can also include an elliptical configuration. As such, the present invention should not be limited to the illustration of the tubular frame 102 and/or 202.

5 The tubular frame 202 further includes elastic regions 228. Typically, the elastic regions 228 can occur at portions of the tubular frame 202 that include curves 230 in the frame members 217. The elastic regions 228 allow the valve 200 to accommodate changes in body lumen size (e.g., diameter of the body lumen) by flexing to expand and/or contract to change the diameter of the tubular frame 202. In one embodiment, the curves 230 in the frame members 217 can act as springs to allow
10 the valve 200 to resiliently radially collapse and expand. The valve frame 202 can also provide sufficient contact and expansion force with the surface of a body lumen wall to encourage fixation of the valve 200 and to prevent retrograde flow within the body lumen. Anchoring elements (e.g., barbs) can also be included with valve 200, as will be discussed herein.

15 The elastic regions 228 of the valve frame 202 allow valve 200 to elastically and repeatably travel between a collapsed state and an expanded state. Figure 3A provides an example of the valve 300 in a collapsed state, and Figure 3B provides an example of the valve 300 in an expanded state. As shown in Figures 3A and 3B, the valve 300 can travel between the collapsed and the expanded state along a radial
20 travel path 336, where there can be a change in a cross sectional area 338 of the lumen 310. For example, the valve frame 302 can travel along the radial travel path 336 so as to change a width 340 of lumen 310. This can allow the valve 300 to react appropriately to any distension and contraction of the lumen in which the valve 300 is placed.

25 In addition to the curves 230, the elastic regions 228 can further include, but are not limited to, other shapes for the valve frame 202 that allow for repeatable travel between the collapsed state and the expanded state. For example, the elastic regions 228 can include integrated springs having a circular or an elliptical coil configuration. Other shapes are also possible.

30 Frame member 217 of the valve frame 202 can include a variety of cross-sectional shapes and dimensions. For example, cross-sectional shapes for the frame member 217 can include, but are not limited to, circular, tubular, I-shaped, T-shaped, oval, trapezoidal, and triangular. The frame member 217 can also have a single cross-sectional shape (e.g., all of valve frame 202 can have a circular cross-sectional shape).

In an additional embodiment, the frame member 217 can have two or more cross-sectional shapes (e.g., a circular cross-sectional shape in the elastic region 228 and a different cross-sectional shape in other regions of valve frame 202).

Valve frame 202 can also include one or more contiguous frame member 217.

5 For example, the frame member 217 of valve frame 202 can be a single contiguous member. The single contiguous member can be bent around an elongate tubular mandrel to form the valve frame 202. The free ends of the single contiguous member can then be welded, fused, crimped, or otherwise joined together to form the valve frame 202. In an additional embodiment, the frame member 217 of valve frame 202
10 can be derived (e.g., laser cut, water cut) from a single tubular segment. In an alternative embodiment, methods of joining the frame member 217 to create the elastic region 228 include, but are not limited to, welding, gluing, and fusing the frame member 217. The valve frame 202 can be heat set by a method as is typically known for the material which forms the valve frame 202.

15 The valve frame 202 can be formed from any number of materials. For example, the valve frame 202 can be formed from a biocompatible metal, metal alloy, polymeric material, or combination thereof. As discussed herein, the valve frame 202 can be self-expanding or balloon expandable. In addition, the valve frame 202 can be configured so as to have the ability to move radially between the collapsed state and
20 the expanded state. To accomplish this, the material used to form the valve frame 202 should exhibit a low elastic modulus and a high yield stress for large elastic strains that can recover from elastic deformations. Examples of suitable materials include, but are not limited to, medical grade stainless steel (e.g., 316L), titanium, tantalum, platinum alloys, niobium alloys, cobalt alloys, alginate, or combinations thereof. In
25 an additional embodiment, the valve frame 202 may be formed from a shape-memory material, such as shape memory plastics, polymers, and thermoplastic materials which are inert in the body. Shaped memory alloys having superelastic properties generally made from specific ratios of nickel and titanium, commonly known as nitinol, are also possible materials. Other materials are also possible.

30 Tubular frame 202 can be expanded to provide lumen 210 having any number of sizes. For example, the size of lumen 210 can be determined based upon the type of body lumen and the body lumen size in which the valve 200 is to be placed. In an additional example, there can also be a minimum value for the width 240 for the

tubular frame 202 that ensures that the tubular frame 202 will have an appropriate expansion force against the inner wall of the body lumen in which the valve 200 is being placed. The tubular frame 202 can also include a longitudinal length 242.

5 In one embodiment, the valve frame 202 can further include one or more anchoring elements. For example, the one or more anchoring elements can include, but are not limited to, one or more barbs 243 projecting from the outer surface 206 of the tubular frame 202. The valve 200 can further include one or more radiopaque markers (e.g., tabs, sleeves, welds). For example, one or more portions of the valve frame 202 can be formed from a radiopaque material. Radiopaque markers can be
10 attached to and/or coated onto one or more locations along the valve frame 202. Examples of radiopaque material include, but are not limited to, gold, tantalum, and platinum. The position of the one or more radiopaque markers can be selected so as to provide information on the position, location and orientation of the valve 200 during its implantation.

15 As discussed herein, valve 100 further includes cover 104 having surfaces defining the reversibly sealable opening 116 for unidirectional flow of a liquid through the lumen 110. For the embodiment illustrated in Figures 1A and 1B, the cover 104 extends over at least a portion of the tubular frame 102 to a first connection point 144 and a second connection point 146 on the tubular frame 102. In one
20 example, the first connection point 144 and the second connection point 146 can be located at the first vertex 118 and the second vertex 120 of the tubular frame 102. The cover 104 extends between the first connection point 144 and the second connection point 146 to provide a first valve leaflet 132 and a second valve leaflet 134. The first valve leaflet 132 and the second valve leaflet 134 can form the
25 reversibly sealable opening 116 extending between the first connection point 144 and the second connection point 146. So, for the example shown in Figure 1 the first valve leaflet 132 and the second valve leaflet 134 form the reversibly sealable opening 116 extending between the first vertex 118 and the second vertex 120 of the tubular frame 102.

30 As illustrated, the first valve leaflet 132 and the second valve leaflet 134 include a region 148 of the cover 104 that can move relative the tubular frame 102. The region 148 of the cover 104 can be unbound (i.e., unsupported) by the tubular frame 102 and extends between the first connection point 144 and the second connection point 146 of the valve 100. This configuration permits the reversibly

sealable opening 116 to open and close in response to the fluid pressure differential across the valve leaflets 132 and 134.

For example, under antegrade fluid flow (i.e., positive fluid pressure) from the first end 112 towards the second end 114 of the valve 100, the first and second valve leaflets 132 and 134 can expand toward the inner surface 108 to create an opening through which fluid is permitted to move. In one example, the first valve leaflet 132 and the second valve leaflet 134 can each expand to define a semi-tubular structure when fluid opens the reversibly sealable opening 116. An example of the open configuration for the valve is shown in Figures 1A and 2A.

Under a retrograde fluid flow (i.e., negative fluid pressure) from the second end 114 towards the first end 112, the first and second valve leaflets 132 and 134 can move away from the inner surface 108 as the valve leaflets 132 and 134 begin to close valve 100. In one example, a pocket exists between the frame 102 and each of the first and second valve leaflets 132 and 134. The pocket allows fluid from the retrograde flow to develop pressure on a first major face 150 of the first and second valve leaflets 132 and 134. As fluid pressure develops, the first and second valve leaflets 132 and 134 collapse, closing the reversibly sealable opening 116 to create a seal 154, thereby restricting retrograde fluid flow through the valve 100. In one example, the seal 154 can be created by the joining of a sealing surface 156 of the first and second valve leaflets 132 and 134. In the closed configuration, the first and second valve leaflets 132 and 134 can each have a concave structure 158 when fluid closes the reversibly sealable opening 116. An example of the closed configuration for the valve is shown in Figures 1B and 2B.

Valve 100 provides an embodiment in which the surfaces defining the reversibly sealable opening 116 provide a bi-leaflet configuration (i.e., a bicuspid valve) for valve 100. Although the embodiments in Figures 1A-B and 2A-D illustrate and describe a bi-leaflet configuration for the valve of the present invention, designs employing a different number of valve leaflets (e.g., tri-leaflet valve) are possible. For example, additional connection points (e.g., three or more) could be used to provide additional valve leaflets (e.g., a tri-leaflet valve).

The first valve leaflet 132 and the second valve leaflet 134 can have a variety of sizes and shapes. For example, each of the first valve leaflet 132 and the second

valve leaflet 134 can have a similar size and shape. In addition, each of the first valve leaflet 132 and the second valve leaflet 134 can include opposed first and second major surfaces 150 and 152, respectively. Each first major surface 150 of the first valve leaflet 132 and the second valve leaflet 134 can be oriented to face the second end 114 of valve 100.

Each of the first valve leaflet 132 and the second valve leaflet 134 can further provide the sealing surface 156 formed by portions of the first valve leaflet 132 and the second valve leaflet 134, where the sealing surface 156 can engage to define the closed configuration (Figure 1B) of valve 100. Sealing surface 156 of the first valve leaflet 132 and the second valve leaflet 134 can separate to provide for an open configuration (Figure 1A) of valve 100. In an additional example, each of the first valve leaflet 132 and the second valve leaflet 134 need not have a similar size and shape (i.e., the valve leaflets can have a different size and shape with respect to each other).

In one embodiment, each of the first valve leaflet 132 and the second valve leaflet 134 includes sufficient excess material spanning tubular frame 102 such that fluid pressure (e.g., antegrade flow) acting on the second major surface 152 of the first valve leaflet 132 and the second valve leaflet 134 forces the valve 100 into an open configuration (Figure 1A). The first valve leaflet 132 and the second valve leaflet 134 further include arcuate edges 160 and 162 that are positioned adjacent each other along a substantially catenary curve between the connection point 144 and the second connection point 146 in the closed configuration (Figure 1B) of valve 100. Similarly, arcuate edges 160 and 162 can define opening 116 when the valve 100 is in the open configuration (Figure 1A).

In an additional embodiment, in the open configuration the portion of the cover 104 forming the first valve leaflet 132 and the second valve leaflet 134 provides sufficient excess material spanning between the connection point 144 and the second connection point 146 to allow the first and second major surfaces 150 and 152 to take on a semi-tubular structure 164, as shown in Figure 1A, when fluid pressure opens the valve 100. In an additional embodiment, arcuate edge 160 and 162 of valve 100 can open to approximately the full inner diameter of a body lumen.

Each of the second major surfaces 152 of the first valve leaflet 132 and the second valve leaflet 134 can further include a curve imparted thereto so as to provide the second major surface 152 with the structure 158. The concave structure 158

allows the first valve leaflet 132 and the second valve leaflet 134 to better collect retrograde fluid flow to urge the first valve leaflet 132 and the second valve leaflet 134 towards the closed configuration. For example, as retrograde flow begins, the first valve leaflet 132 and the second valve leaflet 134 respond by moving towards the center of valve 100. As the first valve leaflet 132 and the second valve leaflet 134 approach the center of the device the sealing surfaces 156 make sufficient contact to effectively close valve 100 and restrict retrograde fluid flow.

In an additional embodiment, the first valve leaflet 132 and the second valve leaflet 134 can include one or more support structures, where the support structures can be integrated into and/or onto the valve leaflets 132 and 134. For example, the first valve leaflet 132 and the second valve leaflet 134 can include one or more support ribs having a predetermined shape. In one embodiment, the predetermined shape of the support ribs can include a curved bias so as to provide the first valve leaflet 132 and the second valve leaflet 134 with a curved configuration. Support ribs can be constructed of a flexible material and have dimensions (e.g., thickness, width and length) and cross-sectional shape that allows the support ribs to be flexible when the first valve leaflet 132 and the second valve leaflet 134 are urged into an open position, and stiff when the first valve leaflet 132 and the second valve leaflet 134 are urged into a closed position upon experiencing sufficient back flow pressure from the direction downstream from the valve. In an additional embodiment, support ribs can also be attached to valve frame 102 so as to impart a spring bias to the valve leaflets in either the open or the closed configuration.

In one embodiment, the material of the first valve leaflet 132 and the second valve leaflet 134 can be sufficiently thin and pliable so as to permit radially-collapsing of the valve leaflets for delivery by catheter to a location within a body lumen. The first valve leaflet 132 and the second valve leaflet 134 can be constructed of a fluid-impermeable biocompatible material that can be either synthetic or biologic. Possible synthetic materials include, but are not limited to, expanded polytetrafluoroethylene (ePTFE), polytetrafluoroethylene (PTFE), polystyrene-polyisobutylene-polystyrene (SIBS), polyurethane, segmented poly(carbonate-urethane), Dacron, polyethylene (PE), polyethylene terephthalate (PET), silk, urethane, Rayon, Silicone, or the like. Possible biologic materials include, but are not limited to, autologous, allogeneic or xenograft material. These include explanted

veins and decellularized basement membrane materials, such as small intestine submucosa (SIS) or umbilical vein.

As discussed herein, the cover 104 can be located over at least the outer surface 106 of the tubular frame 102. Figures 1A and 1B illustrate this embodiment.

5 In an additional embodiment, the cover 104 can also be located over at least the inner surface 108 of the tubular frame 102. Figures 2A-2D illustrate of this embodiment.

In one example, the cover 104 can further be located over the openings 119 defined by the members 117 of the tubular frame 102. The cover 104 can also be joined to itself through the openings 119 so as to fully or partially encase the tubular frame 102.

10 Numerous techniques may be employed to laminate or bond cover 104 on the outer surface 106 and/or the inner surface 108 of the tubular frame 102, including heat setting, adhesive welding, application of uniform force and other bonding techniques. Additionally, the cover 104 may be folded over the first end of the tubular frame 102 to provide the cover 104 on both the outer surface 106 and the inner surface 108.

15 Cover 104 can also be joined to itself and/or the members 117 according to the methods described in U. S. Patent Application Publication US 2002/0178570 to Sogard et al., which is hereby incorporated by reference in its entirety.

The cover 104 can also be coupled to the connection points so as to form the valve leaflets, as discussed herein. In one embodiment, the cover 104 can be in the
20 form of a sheet or a sleeve of material, as discussed herein, which can be connected to the tubular frame 102. Alternatively, the cover 104 can initially be in the form of a liquid that can be used to cast and/or form the cover over the tubular frame 102. Other forms, including intermediate forms, of the cover 104 are also possible.

The cover 104 can be coupled to the tubular frame 102, including the
25 connection points 144 and 146, in a variety of ways so as to provide the various embodiments of the valve of the present invention. For example, a variety of fasteners can be used to couple the cover 104 to the tubular frame 102 so as to form the valve 100. Suitable fasteners can include, but are not limited to, biocompatible staples, glues, sutures or combinations thereof. In an additional embodiment, the
30 cover 104 can be coupled to the tubular frame 102 through the use of heat sealing, solvent bonding, adhesive bonding, or welding cover 104 to either a portion of the cover 104 (i.e., itself) and/or the tubular frame 102.

The cover 104, including the valve leaflets 132 and 134, may also be treated and/or coated with any number of surface or material treatments. For example, the

cover 104 can be treated with one or more biologically active compounds and/or materials that may promote and/or inhibit endothelization and/or smooth muscle cell growth of the cover 104, including the valve leaflets 132 and 134. Similarly, the cover 104 may be seeded and covered with cultured tissue cells (e.g., endothelial cells) derived from either a donor or the host patient which are attached to the valve leaflets 132 and 134. The cultured tissue cells may be initially positioned to extend either partially or fully over the valve leaflets 132 and 134.

Cover 104, in addition to forming valve leaflets 132 and 134, can also be capable of inhibiting thrombus formation. Additionally, cover 104 may either prevent or facilitate tissue ingrowth therethrough, as the particular application for the valve 100 may dictate. For example, cover 104 on the outer surface 106 may be formed from a porous material to facilitate tissue ingrowth therethrough, while cover 104 on the inner surface 108 may be formed from a material or a treated material which inhibits tissue ingrowth.

The embodiments of the valve of the present invention can be formed in any number of ways. For example, Figures 4A-4D provide an illustration of a method for forming valve 400. Figure 4A illustrates one embodiment of cover 404 having a tubular configuration that includes a symmetrical portion 466 and a tapering portion 468. In the present example, the cover 404 can be formed from a continuous piece of tubular material. In one example, the tapering portion 468 can be formed by removing predetermined portions of the tubular material from the continuous piece of tubular material.

For example, Figures 5A-5C illustrate one embodiment of creating a tapering portion 568 for the cover 504. Cover 504 is shown in a flattened configuration to better illustrate forming the tapering portion 568 according to the present embodiment. As Figure 5A illustrates, cover 504 can have an initial symmetrical configuration. Figure 5A also illustrates that a portion 569, defined by line 570, of the cover 504 in the symmetrical configuration for removal in forming the tapering portion. Figure 5B shows the portion 569 removed from the cover 504. Once removed, the cover 504 includes edges 571 that are joined to form the tapering portion 568. Figure 5C provides an example of edges 571 joined for the tapering portion 568. In one example, the edges 571 can be joined in any number of ways, including any of those recited herein.

Other ways of forming the tapering portion 468 during the manufacturing of the cover 404 also exist. For example, the cover 404 can be cast, extruded, or molded (including blow molded) to form the tapering portion 468. In addition, tapering portion 468 can be provided separately from the symmetrical portion 466. In other words, each portion (e.g., tapering portion 468 and the symmetrical portion 466) are
5 separate pieces that can either be then be joined, by method described herein, or used separately in forming valve 400.

In an alternative embodiment, the tapering portion 468 can be created as a result of at least a portion of the cover 404 being stretched over the tubular frame 402.
10 For example, the cover 404 can have a cylindrical shape of essentially uniform inner diameter, where the inner diameter is less than an outer diameter of the tubular frame 402. The cover 404 can be stretched over the outer surface 406 of the tubular frame 402 such that the tapering portion 468 results as the cover 404 transitions from its stretched portion over the tubular frame 402 to the unstretched portion of the cover
15 404.

Referring again to Figures 4B-4D, the symmetrical portion 466 of the cover 404 can be placed around the outer surface 406 of the tubular frame 402. For example, the cover 404 can stretched slightly to allow the tubular frame 402 to be placed within the symmetrical portion 466 of the cover 404. Alternatively, the outer
20 diameter of the tubular frame 402 could be enlarged so as to place the symmetrical portion 466 of the cover 404 around the outer surface 406 of the tubular frame 402. Other ways of placing the symmetrical portion 466 of the cover 404 around the outer surface 406 of the tubular frame 402 are also possible.

As Figure 4C illustrates, a free end 472 of the tapering portion 468 can be
25 folded and drawn into the lumen 410 of the tubular frame 402. The free end 472 is advanced toward the second end 414, so that the cover 404 extends over at least a portion of the inner surface 408 of the tubular frame 402. The free end 472 of the cover 404 can extend over at least the portion of the inner surface 408 to at least a first connection point 444 and a second connection point 446 on the tubular frame 402. As
30 Figure 4D illustrates, the cover 404 can be attached at the first connection point 444 and the second connection point 446 to form the first valve leaflet 432 and the second valve leaflet 434. As discussed herein, the first valve leaflet 432 and the second valve leaflet 434 include sealing surfaces 456 defining the reversibly sealable opening 416 for unidirectional flow of liquid through the lumen 410.

Figure 4D further illustrates the cover 404 located over the outer surface 406 may be affixed to the cover 404 over at least a portion of the inner surface 408 through the openings 419 and/or affixed to the members 417 of the tubular frame 402. In addition, the cover 404 located over the outer surface 406 may be affixed at least to the members 417 of the tubular frame 402.

Figure 6A-6E provides an alternative embodiment of forming a valve 600. In the present embodiment, the cover 604 can include at least two separate portions (e.g., symmetrical portion 666 shown in Figure 6A and tapering portion 668 shown in Figure 6B) that are affixed to the tubular frame 602 to form the valve 600. For example, the cover 604 can be formed from a symmetrical portion 666, shown in Figure 6A, that is separate from a tapering portion 668, shown in Figure 6B.

The tapering portion 668 and the symmetrical portion 666 can be affixed to the tubular frame 602 and to each other, as described herein, so as to form valve 600. For example, Figures 6C-6D illustrate symmetrical portion 666 affixed to tubular frame 602, with tapering portion 668 being inserted into lumen 610. Figure 6E illustrates valve 600 upon affixing the tapering portion 668 to the symmetrical portion 666, the tubular frame 602 and the first and second connection points 644 and 646.

Figures 7A-7D illustrate an additional embodiment of forming a valve 700 according to the present invention. The valve 700 includes tubular frame 702 (Figure 7A) and cover 704 (Figure 7B). As discussed herein, tubular frame 702 has an open frame configuration that includes the first vertex 718 and a second vertex 720 relative the first end 712 of the tubular frame 702. In the present example, the cover 704 can have a tubular configuration, where the cover 704 can be positioned around and affixed to the tubular frame 702 (Figures 7C-7D) so as to form valve 700. For example, cover 704 and/or tubular frame 702 can be stretched so as to affix the cover 704 and the tubular frame 702. In addition, the cover 704 can be affixed to the tubular frame 702 by additional mechanical and/or chemical approaches, as discussed herein.

Figure 8 illustrates one embodiment of a system 882. System 882 includes valve 800, as described herein, reversibly joined to catheter 874. The catheter 874 includes an elongate body 876 having a proximal end 878 and a distal end 879, where valve 800 can be located between the proximal end 878 and distal end 879. The catheter 874 can further include a lumen 880 longitudinally extending to the distal end 879. In one embodiment, lumen 880 extends between proximal end 878 and distal

end 879 of catheter 874. The catheter 874 can further include a guidewire lumen 881 that extends within the elongate body 876, where the guidewire lumen 881 can receive a guidewire for positioning the catheter 874 and the valve 800 within a body lumen (e.g., a vein of a patient).

5 The system 882 can further include a deployment shaft 883 positioned within lumen 880, and a sheath 884 positioned adjacent the distal end 879. In one embodiment, the valve 800 can be positioned at least partially within the sheath 884 and adjacent the deployment shaft 883. The deployment shaft 883 can be moved within the lumen 880 to deploy valve 800. For example, deployment shaft 883 can be
10 used to push valve 800 from sheath 884 in deploying valve 800.

 Figure 9 illustrates an additional embodiment of the system 982. The catheter 974 includes elongate body 976, lumen 980, a retraction system 986 and a retractable sheath 987. The retractable sheath 987 can be positioned over at least a portion of the elongate body 976, where the retractable sheath 987 can move longitudinally along
15 the elongate body 976. The valve 900 can be positioned at least partially within the retractable sheath 987, where the retractable sheath 987 moves along the elongate body 976 to deploy the valve 900. In one embodiment, retraction system 986 includes one or more wires coupled to the retractable sheath 987, where the wires are positioned at least partially within and extend through lumen 980 in the elongate body
20 976. Wires of the retraction system 986 can then be used to retract the retractable sheath 987 in deploying valve 900.

 Figure 10 illustrates an additional embodiment of the system 1082. The catheter 1074 includes elongate body 1076, an inflatable balloon 1088 positioned adjacent the distal end 1079, and a lumen 1080 longitudinally extending in the
25 elongate body 1076 of the catheter 1074 from the inflatable balloon 1088 to the proximal end 1078. In the present example, the inflatable balloon 1088 can be at least partially positioned within the lumen 1010 of the valve 1000. The inflatable balloon 1088 can be inflated through the lumen 1080 to deploy the valve 1000.

 The embodiments of the present invention further include methods for forming
30 the valve of the present invention, as discussed herein. For example, the valve can be formed from the tubular frame and the cover over at least the outer surface of the tubular frame, where the cover includes surfaces defining the reversibly sealable opening for unidirectional flow of a liquid through the lumen. In an additional example, the valve can be reversibly joined to the catheter, which can include a

process of altering the shape of the valve from a first shape, for example an expanded state, to the compressed state, as described herein.

For example, the valve can be reversibly joined with the catheter by positioning valve in the compressed state at least partially within the sheath of the catheter. In one embodiment, positioning the valve at least partially within the sheath of the catheter includes positioning the valve in the compressed state adjacent the deployment shaft of the catheter. In an another embodiment, the sheath of the catheter functions as a retractable sheath, where the valve in the compressed state can be reversibly joined with the catheter by positioning the valve at least partially within the reversible sheath of the catheter. In a further embodiment, the catheter can include an inflatable balloon, where the balloon can be positioned at least partially within the lumen of the valve, for example, in its compressed state.

The embodiments of the valve described herein may be used to replace, supplement, or augment valve structures within one or more lumens of the body. For example, embodiments of the present invention may be used to replace an incompetent venous valve and help to decrease backflow of blood in the venous system of the legs.

In one embodiment, the method of replacing, supplementing, and/or augmenting a valve structure can include positioning at least part of the catheter including the valve at a predetermined location within the lumen of a body. For example, the predetermined location can include a position within a body lumen of a venous system of a patient, such as a vein of a leg.

In one embodiment, positioning the catheter that includes the valve within the body lumen of a venous system includes introducing the catheter into the venous system of the patient using minimally invasive percutaneous, transluminal catheter based delivery system, as is known in the art. For example, a guidewire can be positioned within a body lumen of a patient that includes the predetermined location. The catheter, including valve, as described herein, can be positioned over the guidewire and the catheter advanced so as to position the valve at or adjacent the predetermined location. In one embodiment, radiopaque markers on the catheter and/or the valve, as described herein, can be used to help locate and position the valve.

The valve can be deployed from the catheter at the predetermined location in any number of ways, as described herein. In one embodiment, valve of the present

invention can be deployed and placed in any number of vascular locations. For example, valve can be deployed and placed within a major vein of a patient's leg. In one embodiment, major veins include, but are not limited to, those of the peripheral venous system. Examples of veins in the peripheral venous system include, but are not limited to, the superficial veins such as the short saphenous vein and the greater saphenous vein, and the veins of the deep venous system, such as the popliteal vein and the femoral vein.

As discussed herein, the valve can be deployed from the catheter in any number of ways. For example, the catheter can include the retractable sheath in which valve can be at least partially housed, as discussed herein. Valve can be deployed by retracting the retractable sheath of the catheter, where the valve self-expands to be positioned at the predetermined location. In an additional example, the catheter can include a deployment shaft and sheath in which valve can be at least partially housed adjacent the deployment shaft, as discussed herein. Valve can be deployed by moving the deployment shaft through the catheter to deploy valve from the sheath, where the valve self-expands to be positioned at the predetermined location. In an additional embodiment, the valve can be deployed through the use of an inflatable balloon.

Once implanted, the valve can provide sufficient contact and expansion force against the body lumen wall to prevent retrograde flow between the valve and the body lumen wall. For example, the valve can be selected to have a larger expansion diameter than the diameter of the inner wall of the body lumen. This can then allow valve to exert a force on the body lumen wall and accommodate changes in the body lumen diameter, while maintaining the proper placement of valve. As described herein, the valve can engage the lumen so as to reduce the volume of retrograde flow through and around valve. It is, however, understood that some leaking or fluid flow may occur between the valve and the body lumen and/or through valve leaflets.

While the present invention has been shown and described in detail above, it will be clear to the person skilled in the art that changes and modifications may be made without departing from the spirit and scope of the invention. As such, that which is set forth in the foregoing description and accompanying drawings is offered by way of illustration only and not as a limitation. The actual scope of the invention is intended to be defined by the following claims, along with the full range of equivalents to which such claims are entitled.

In addition, one of ordinary skill in the art will appreciate upon reading and understanding this disclosure that other variations for the invention described herein can be included within the scope of the present invention. For example, the tubular frame 102 and/or the cover 104 can be coated with a non-thrombogenic biocompatible material, as are known or will be known.

In the foregoing Detailed Description, various features are grouped together in several embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the embodiments of the invention require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

WHAT IS CLAIMED IS:

1. A valve, comprising:
a tubular frame, wherein the tubular frame includes an outer surface and an inner surface opposite the outer surface and defining a lumen; and
a cover on the tubular frame, wherein the cover includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid through the lumen.
2. The valve of claim 1, wherein the cover on the tubular frame includes the cover on the outer surface of the tubular frame.
3. The valve of claim 1, wherein the tubular frame includes a first vertex and a second vertex relative a first end of the tubular frame, wherein the first vertex and the second vertex are positioned opposite each other along a common axis.
4. The valve of claim 3, wherein the cover extends to at least the first vertex and the second vertex to form a first valve leaflet and a second valve leaflet between the first vertex and the second vertex.
5. The valve of claim 4, wherein the first valve leaflet and the second valve leaflet form the reversibly sealable opening extending between the first vertex and the second vertex.
6. The valve of claim 1, further including the cover on the inner surface of the tubular frame, wherein the cover on the inner surface extends to at least a first connection point and a second connection point on the tubular frame to form a first valve leaflet and a second valve leaflet.
7. The valve of claim 6, wherein the first valve leaflet and the second valve leaflet form the reversibly sealable opening extending between the first connection point and the second connection point.

8. The valve of claim 6, wherein the first valve leaflet and the second valve leaflet include support ribs having a predefined shape.
9. The valve of claim 6, further including the cover on the inner surface and an outer surface of the tubular frame.
10. The valve of claim 1, wherein the tubular frame moves between a collapsed state and an expanded state.
11. The valve of claim 1, further including a catheter having a proximal end and a distal end, the valve of claim 1 located between the proximal end and distal end of the catheter.
12. The valve of claim 11, wherein the catheter includes an elongate body having a lumen longitudinally extending to the distal end, a deployment shaft positioned within the lumen, and a sheath positioned adjacent the distal end, the valve positioned at least partially within the sheath and adjacent the deployment shaft, wherein the deployment shaft moves within the lumen to deploy the valve.
13. The valve of claim 11, wherein the catheter includes an elongate body and a retractable sheath over at least a portion of the elongate body, the valve positioned at least partially within the retractable sheath, wherein the retractable sheath moves along the elongate body to deploy the valve.
14. The valve of claim 11, wherein the catheter includes an inflatable balloon positioned adjacent the distal end and a lumen longitudinally extending in an elongate body of the catheter from the inflatable balloon to the distal end, the inflatable balloon at least partially positioned within the lumen of the valve, where the inflatable balloon inflates to deploy the valve.
15. A method, comprising:
forming a valve that includes:
a tubular frame, wherein the tubular frame includes an outer surface
and an inner surface opposite the outer surface and defining a lumen;

a cover on at least the outer surface of the tubular frame, wherein the cover includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid through the lumen.

16. The method of claim 15, further including reversibly joining the valve and a catheter, wherein reversibly joining the valve and the catheter includes positioning the valve at least partially within a sheath of the catheter.

17. The method of claim 16, wherein positioning the valve at least partially within a sheath of the catheter include positioning the valve adjacent a deployment shaft of the catheter.

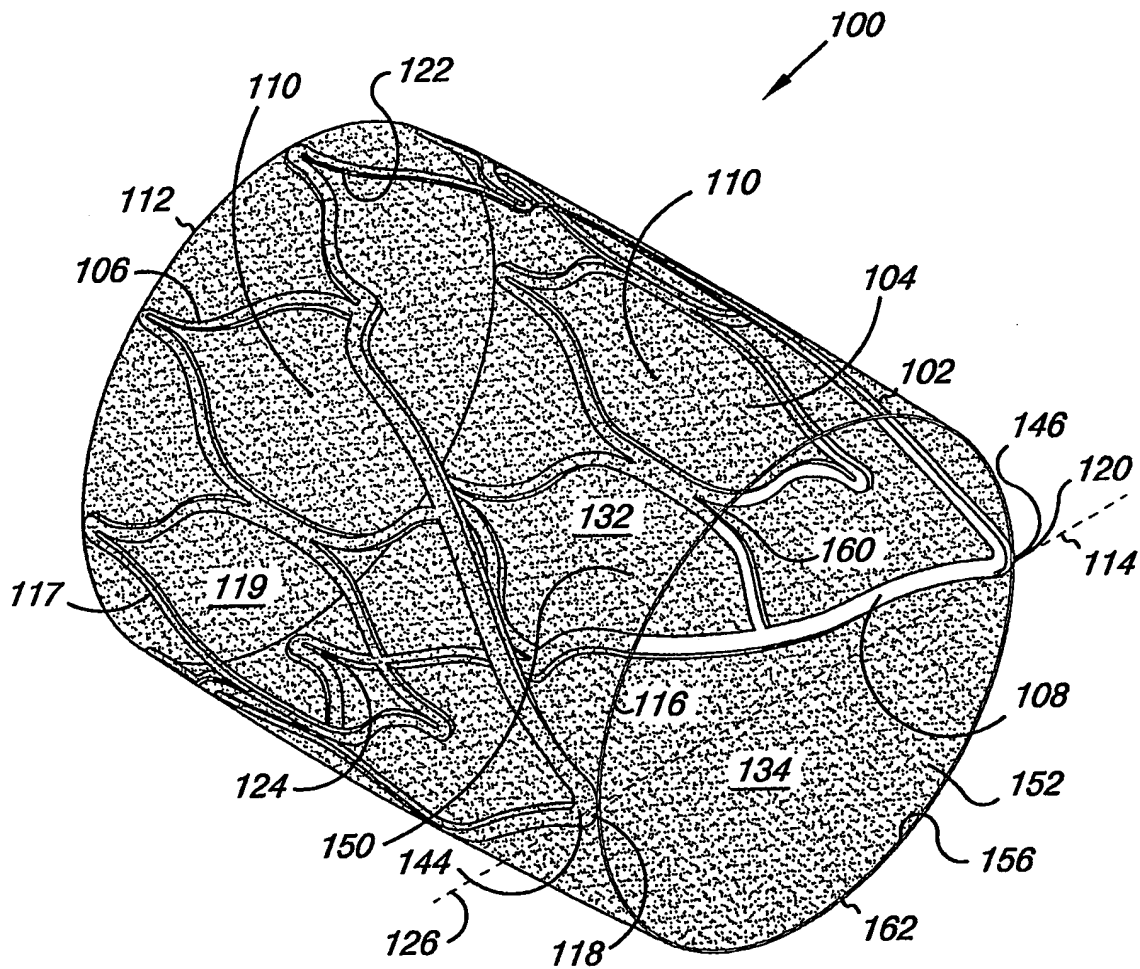
18. The method of claim 16, wherein the sheath includes a retractable sheath of the catheter.

19. The method of claim 15, further including reversibly joining the valve and a catheter, wherein the catheter includes an inflatable balloon, the inflatable balloon at least partially positioned within the lumen of the valve; and
inflating the balloon to deploy the valve.

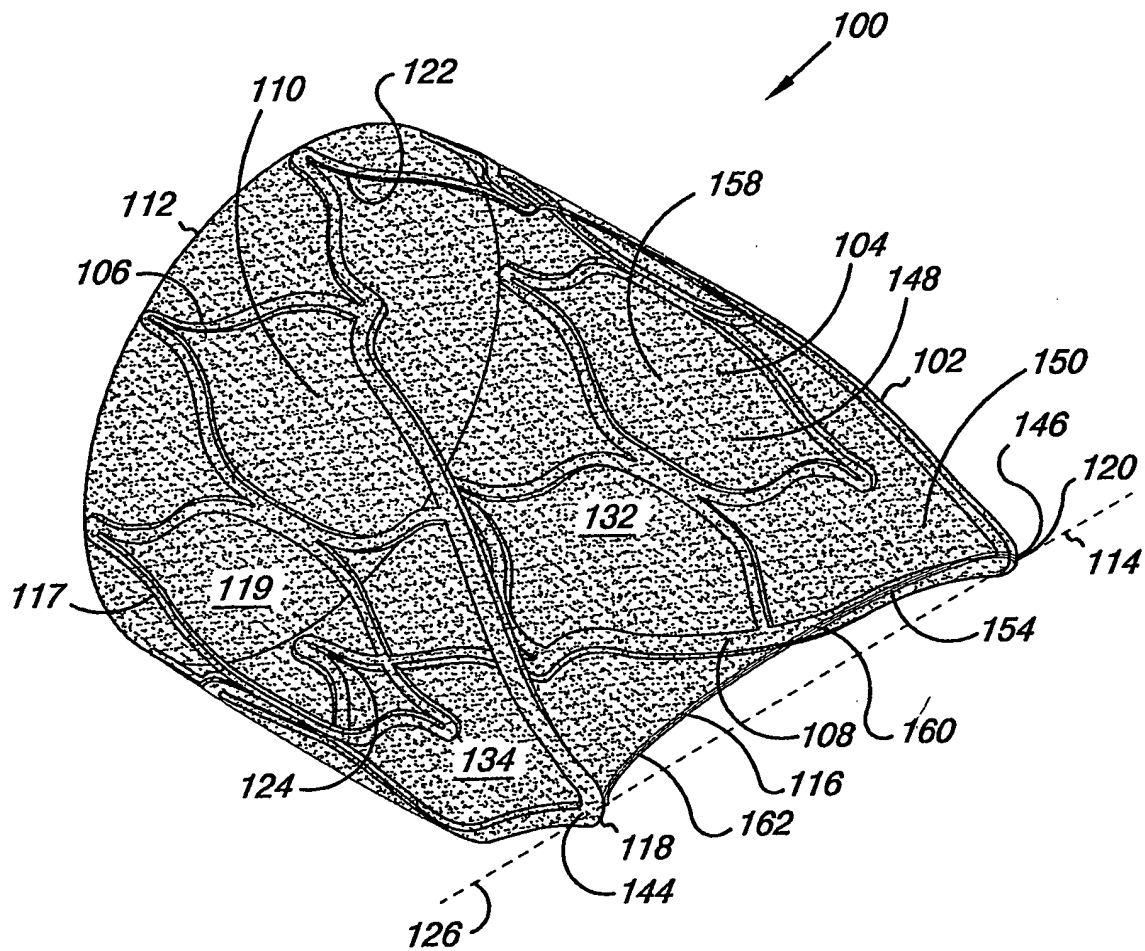
20. The method of claim 15, wherein the tubular frame includes a first vertex and a second vertex relative a first end of the tubular frame, wherein the first vertex and the second vertex are positioned opposite each other along a common axis, where the cover extends to at least the first vertex and the second vertex to form a first valve leaflet and a second valve leaflet between the first vertex and the second vertex, wherein the first valve leaflet and the second valve leaflet includes a surface defining a reversibly sealable opening for unidirectional flow of a liquid through the lumen.

21. The method of claim 15, wherein the cover extends over at least a portion of the inner surface of the tubular frame, wherein the cover on the at least the portion of the inner surface extends to at least a first connection point and a second connection point on the tubular frame to form a first valve leaflet and a second valve leaflet, wherein the first valve leaflet and the second valve leaflet includes a surface defining a reversibly sealable opening for unidirectional flow of a liquid through the lumen.

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*Fig. 1A*

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*Fig. 1B*

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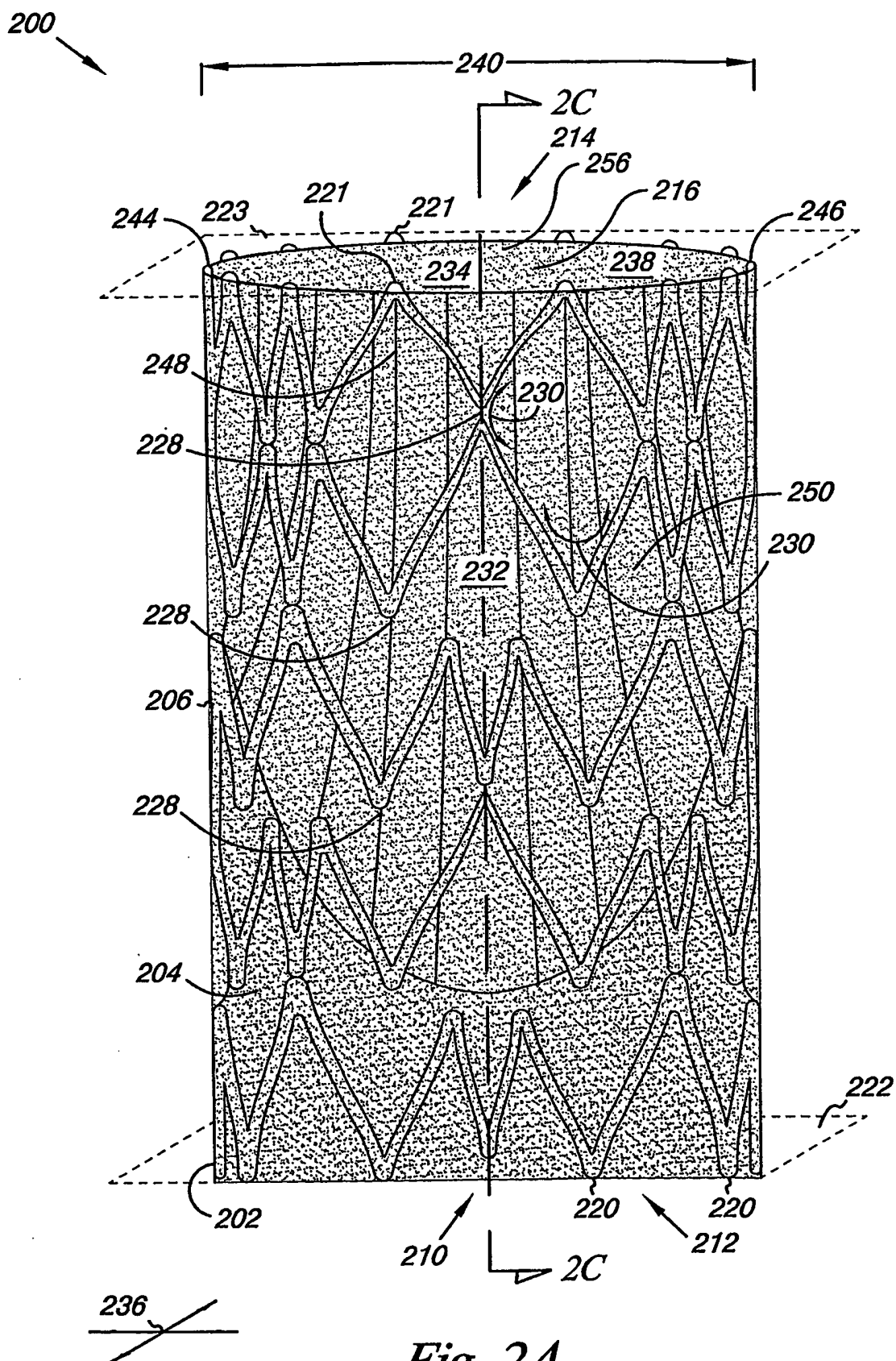


Fig. 2A

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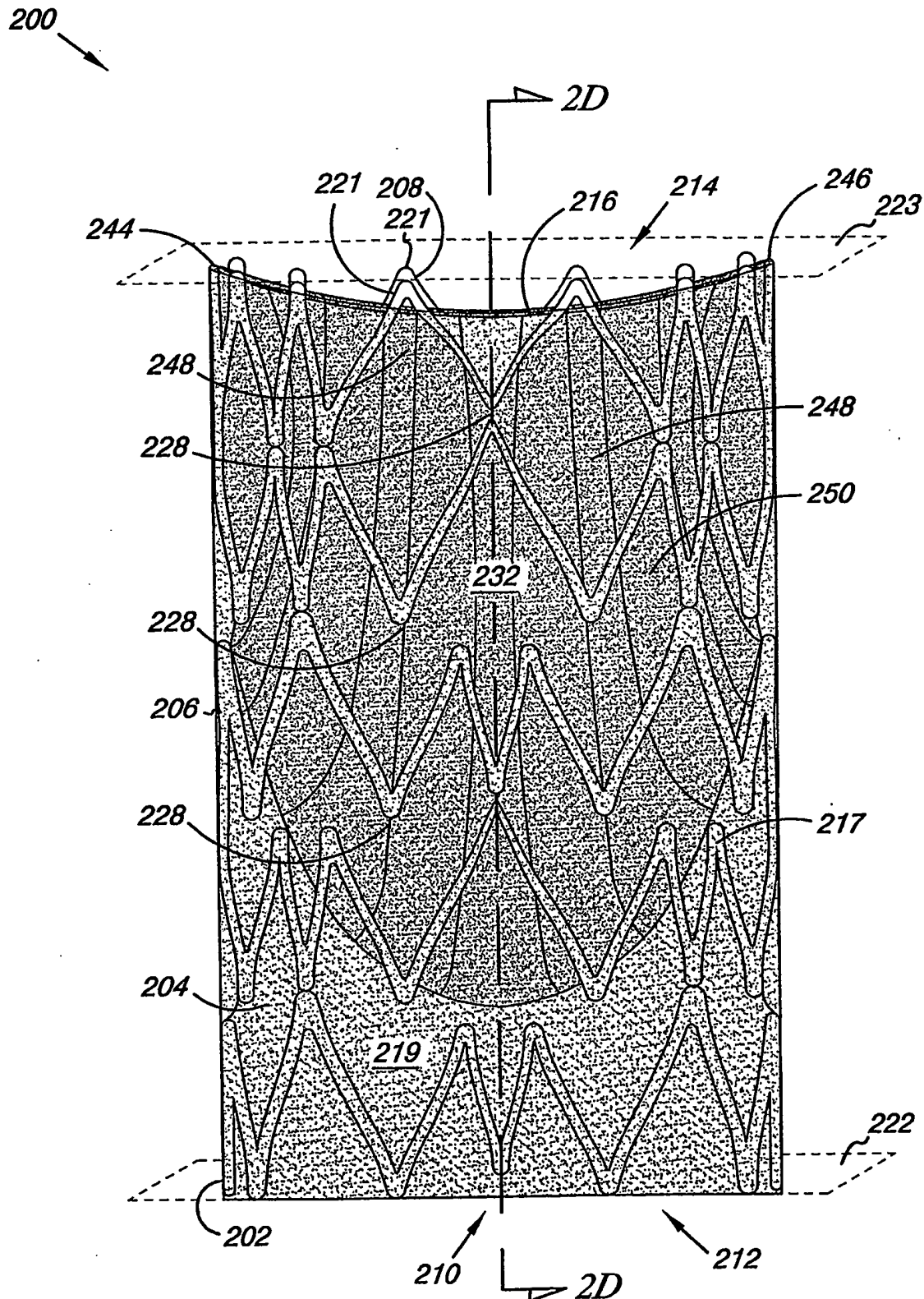


Fig. 2B

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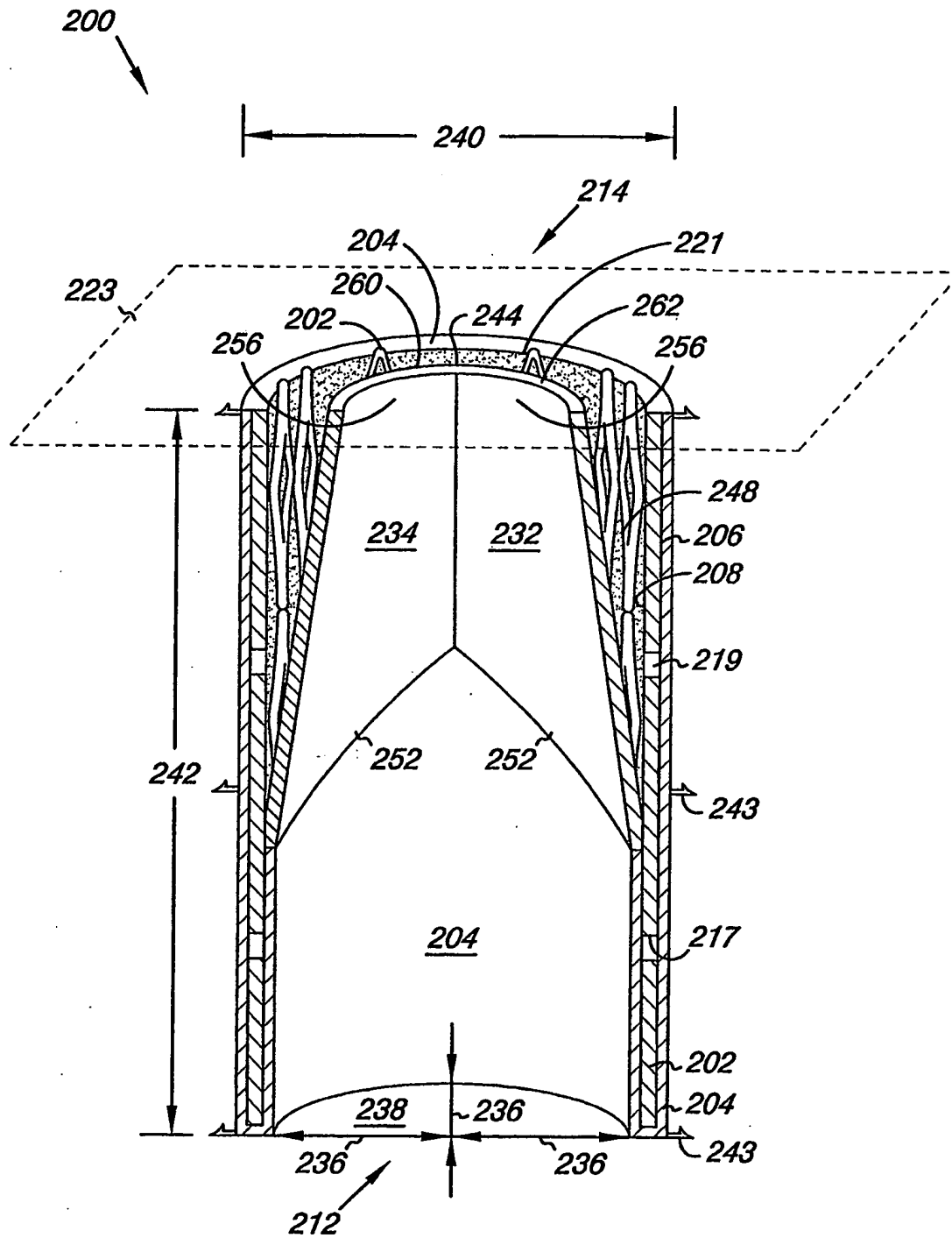
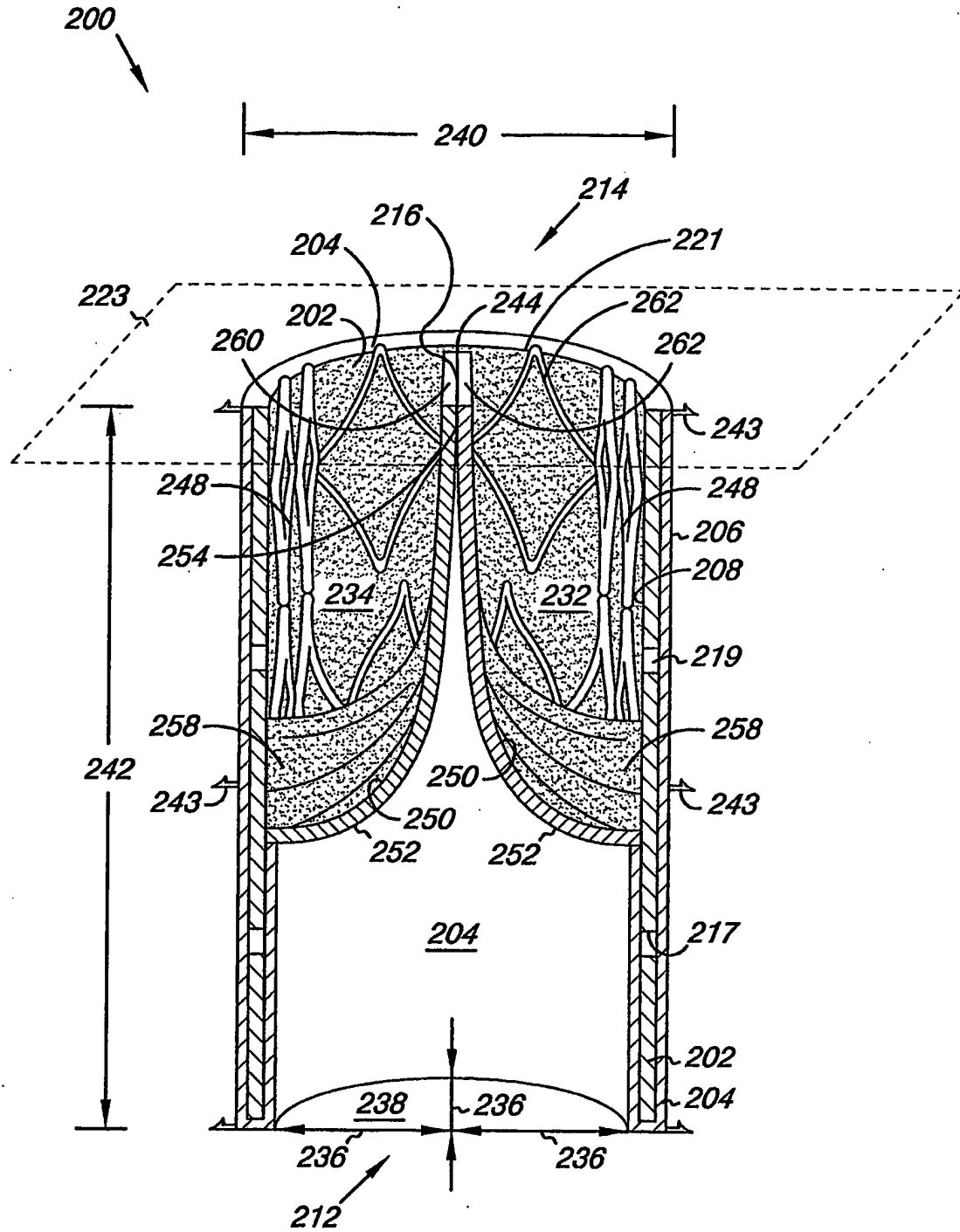


Fig. 2C

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*Fig. 2D*

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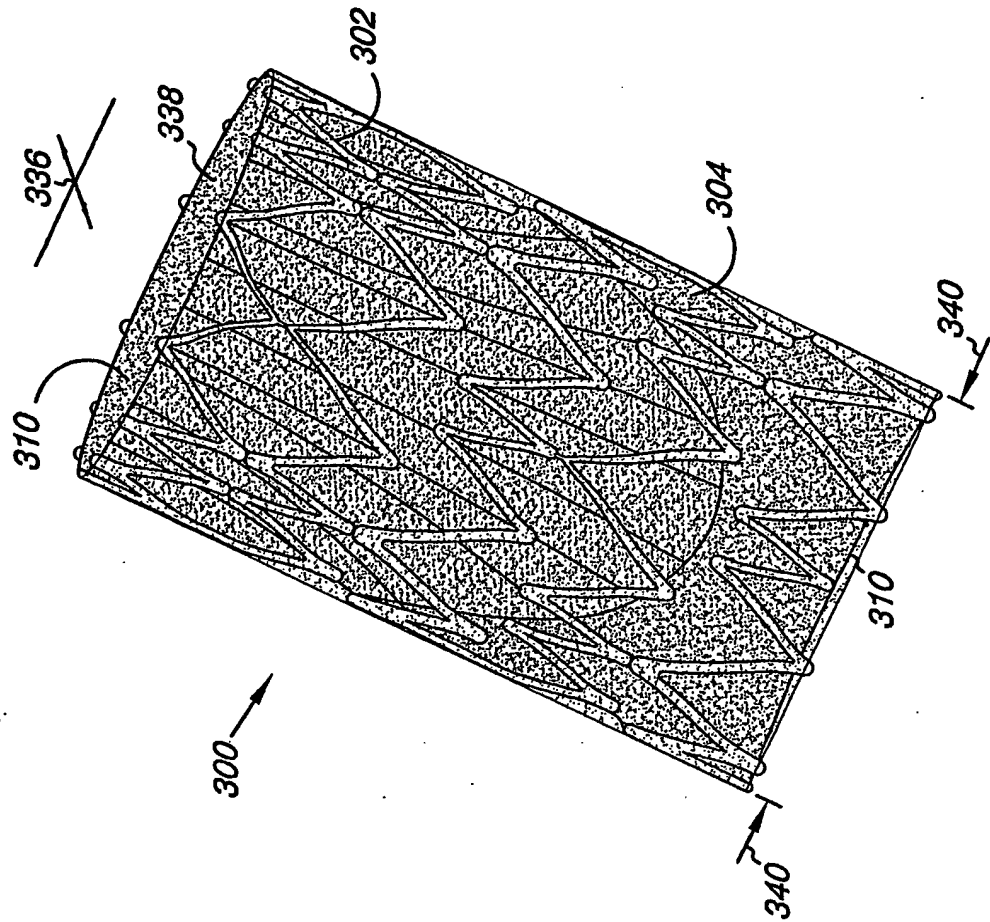


Fig. 3B

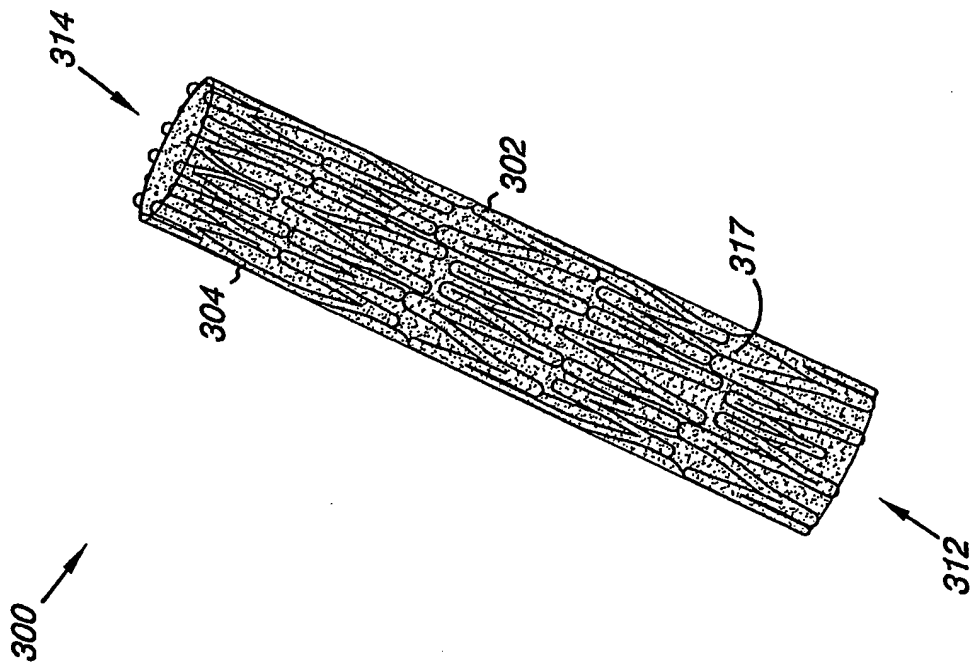


Fig. 3A

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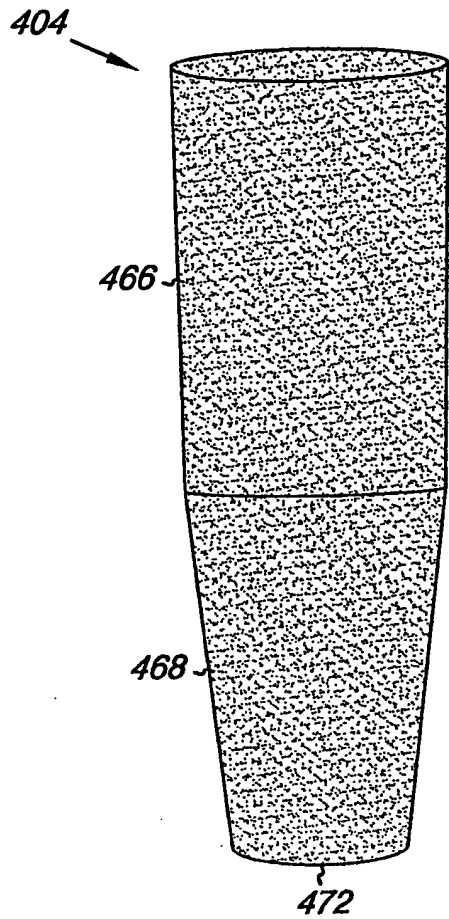


Fig. 4A

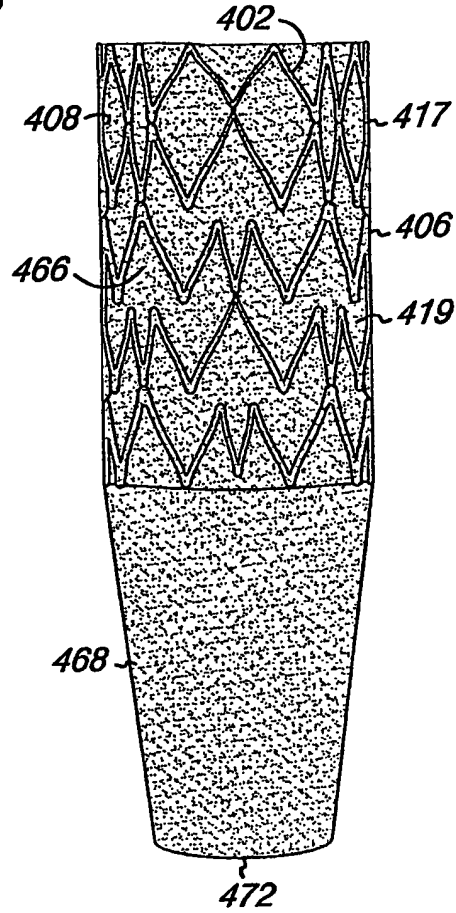


Fig. 4B

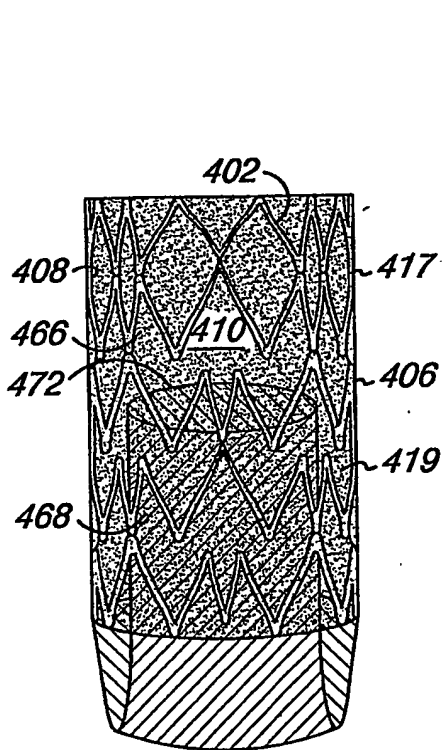


Fig. 4C

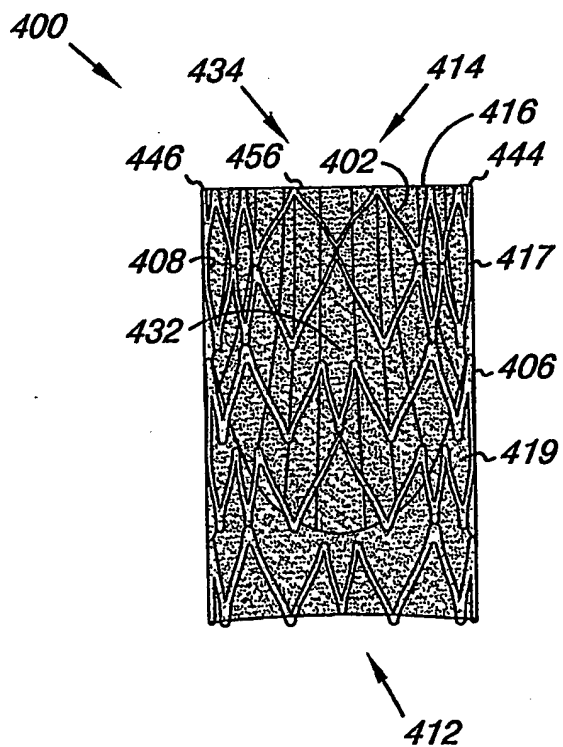


Fig. 4D

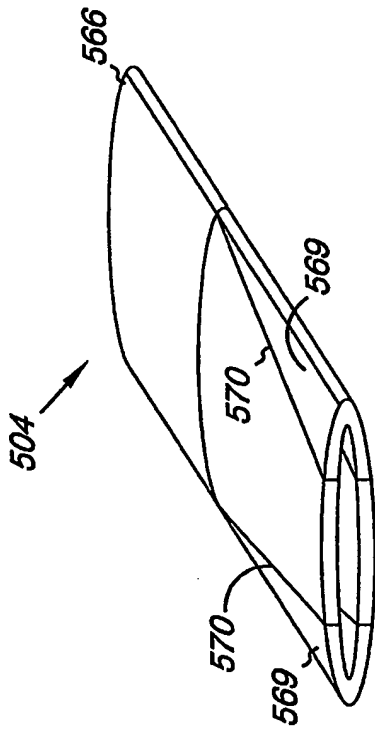


Fig. 5A

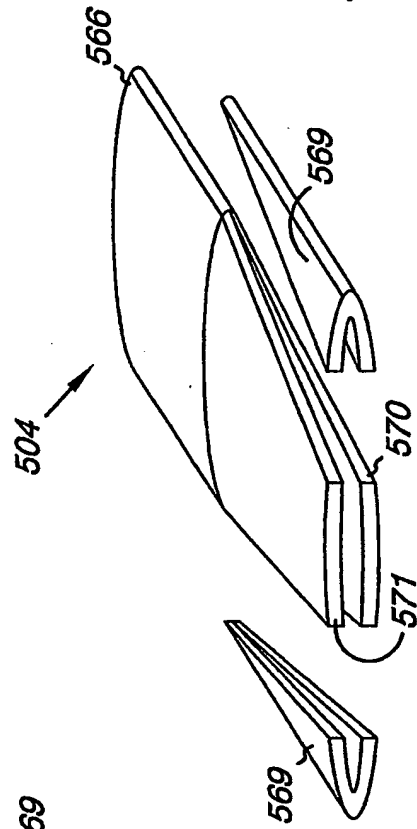


Fig. 5B

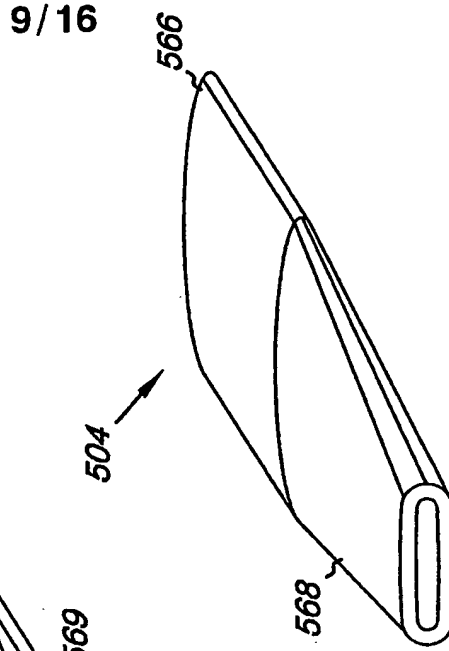


Fig. 5C

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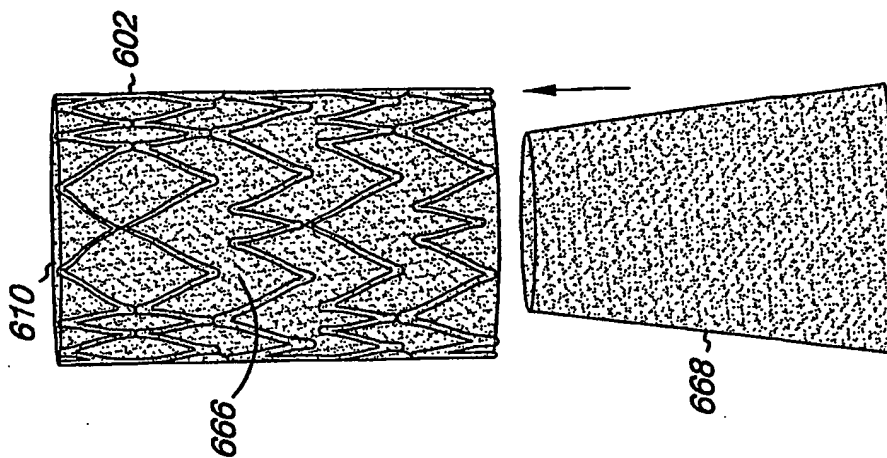


Fig. 6C

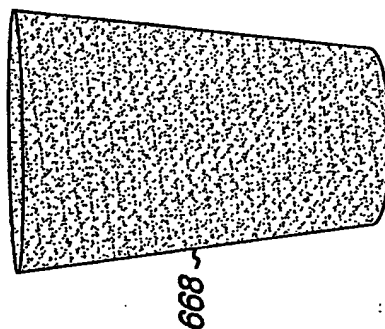


Fig. 6B

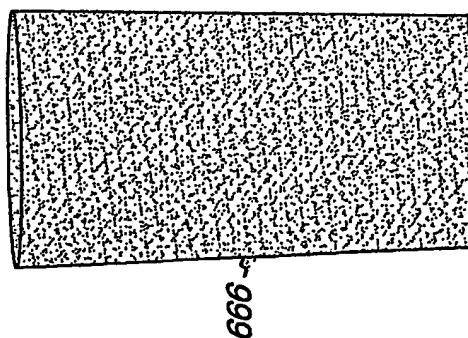


Fig. 6A

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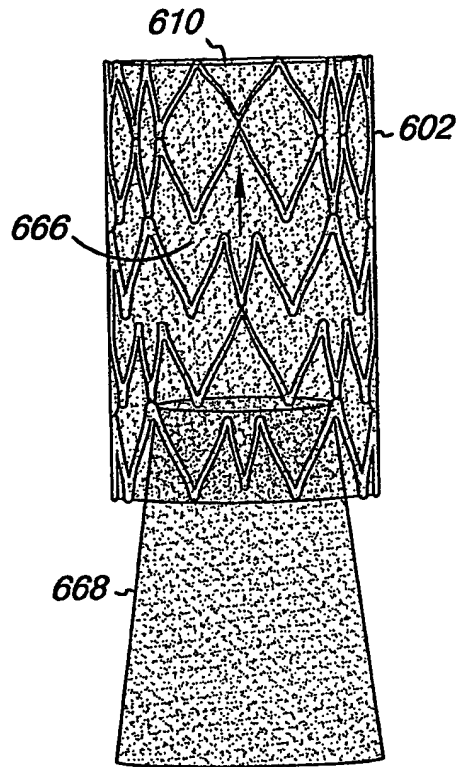


Fig. 6D

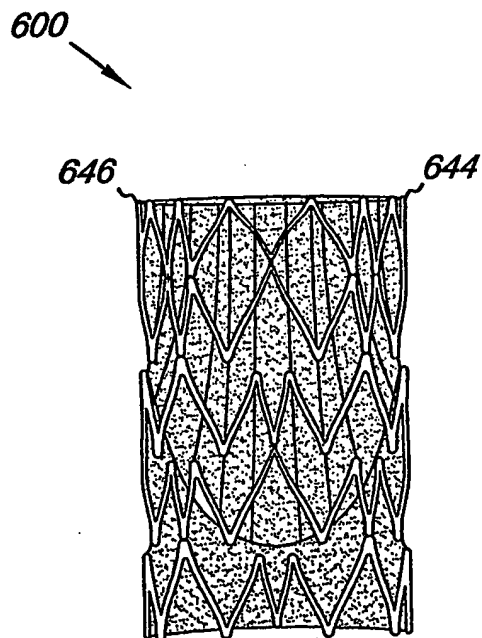
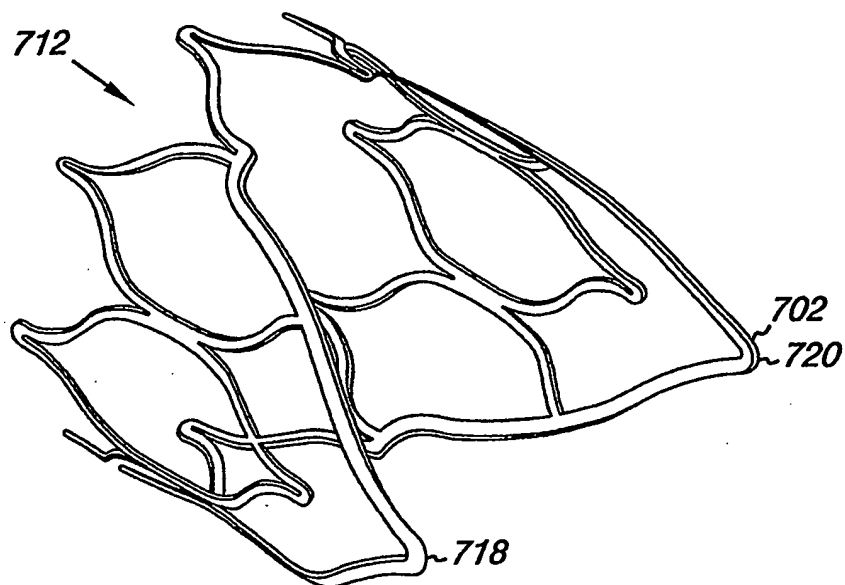
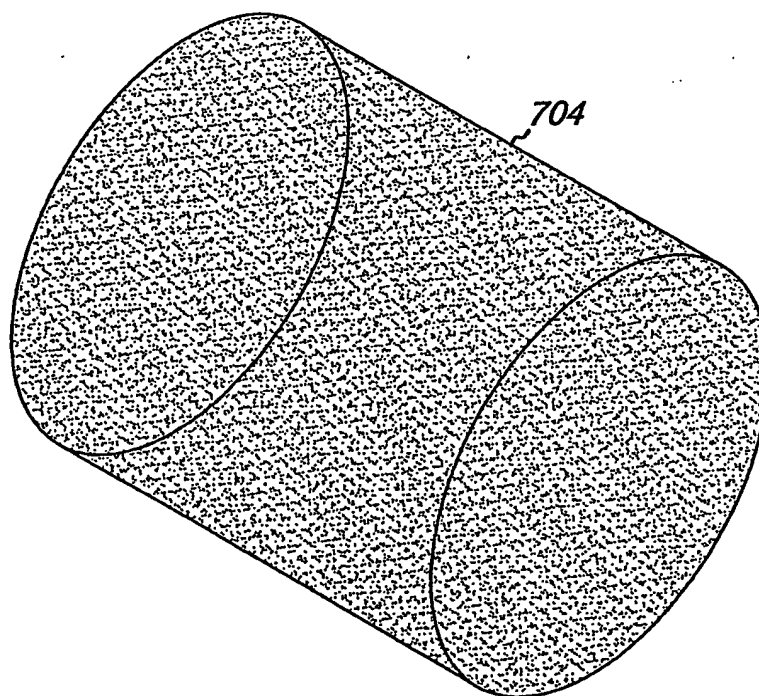


Fig. 6E

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*Fig. 7A**Fig. 7B*

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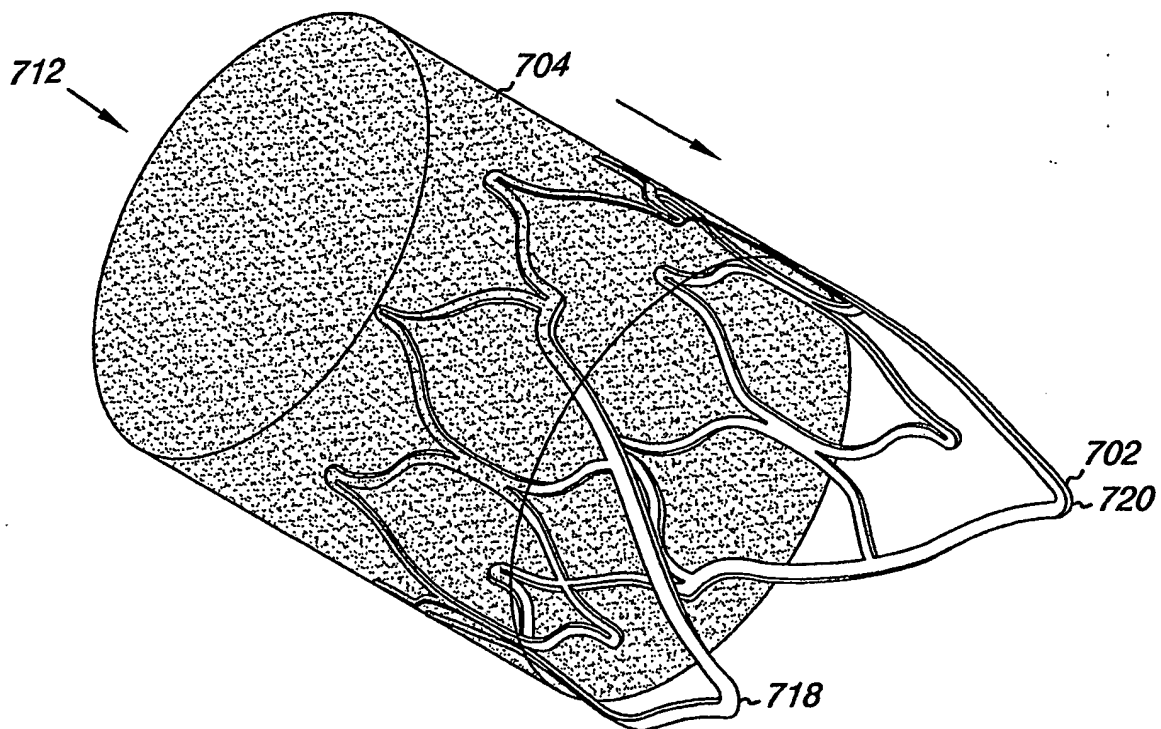


Fig. 7C

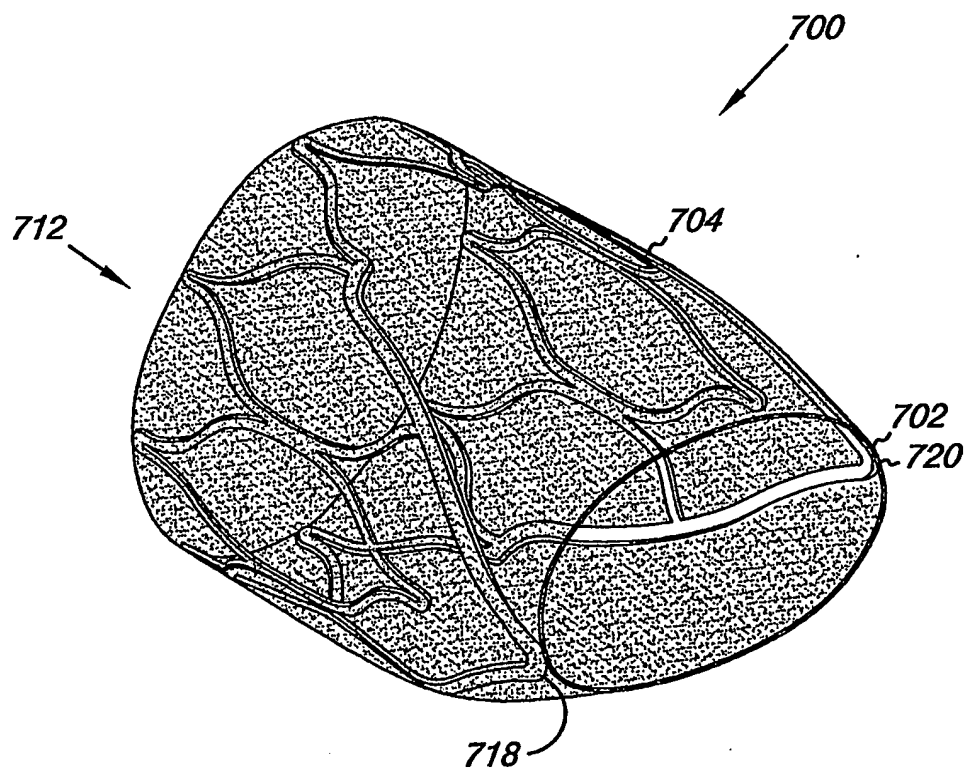
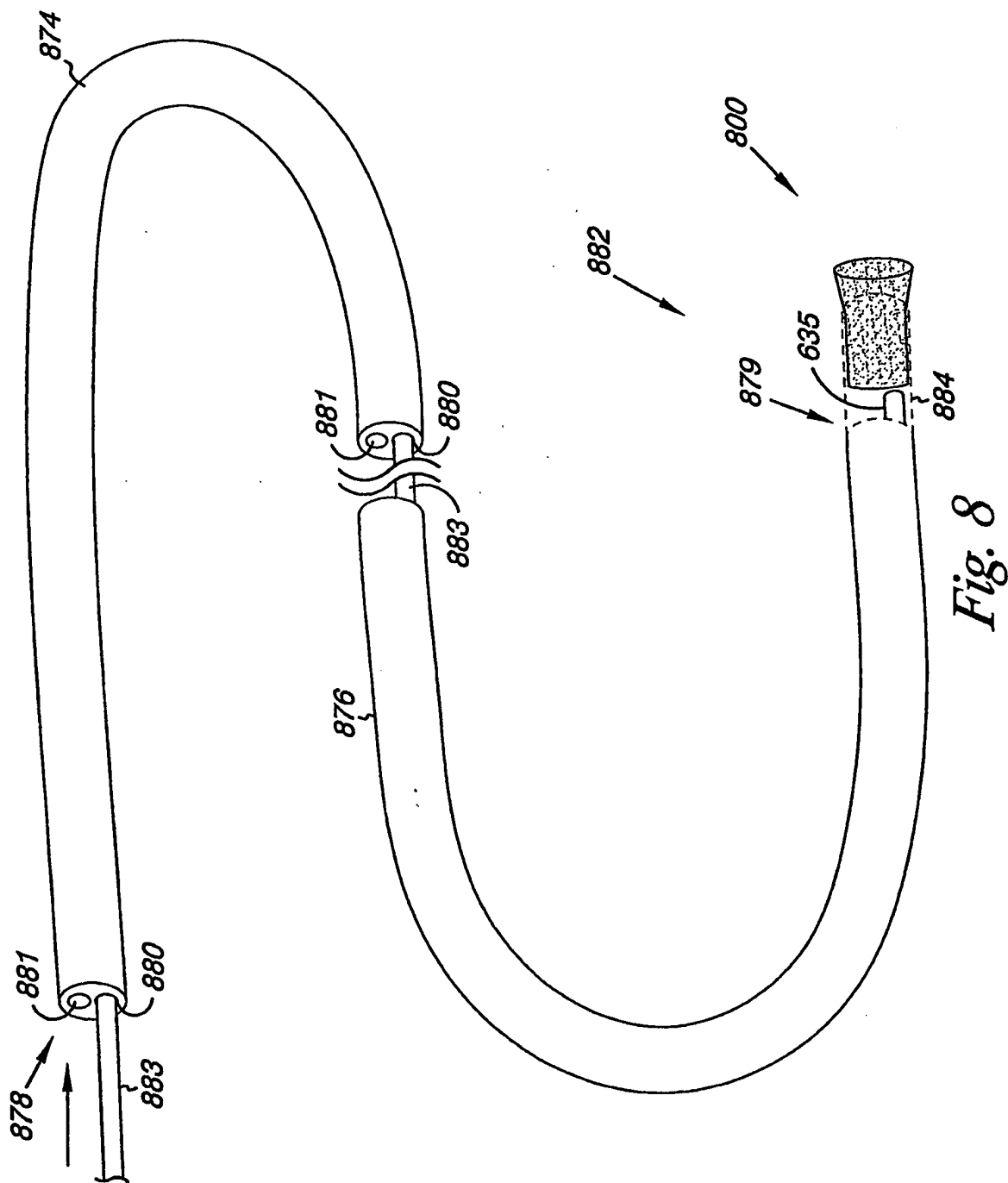
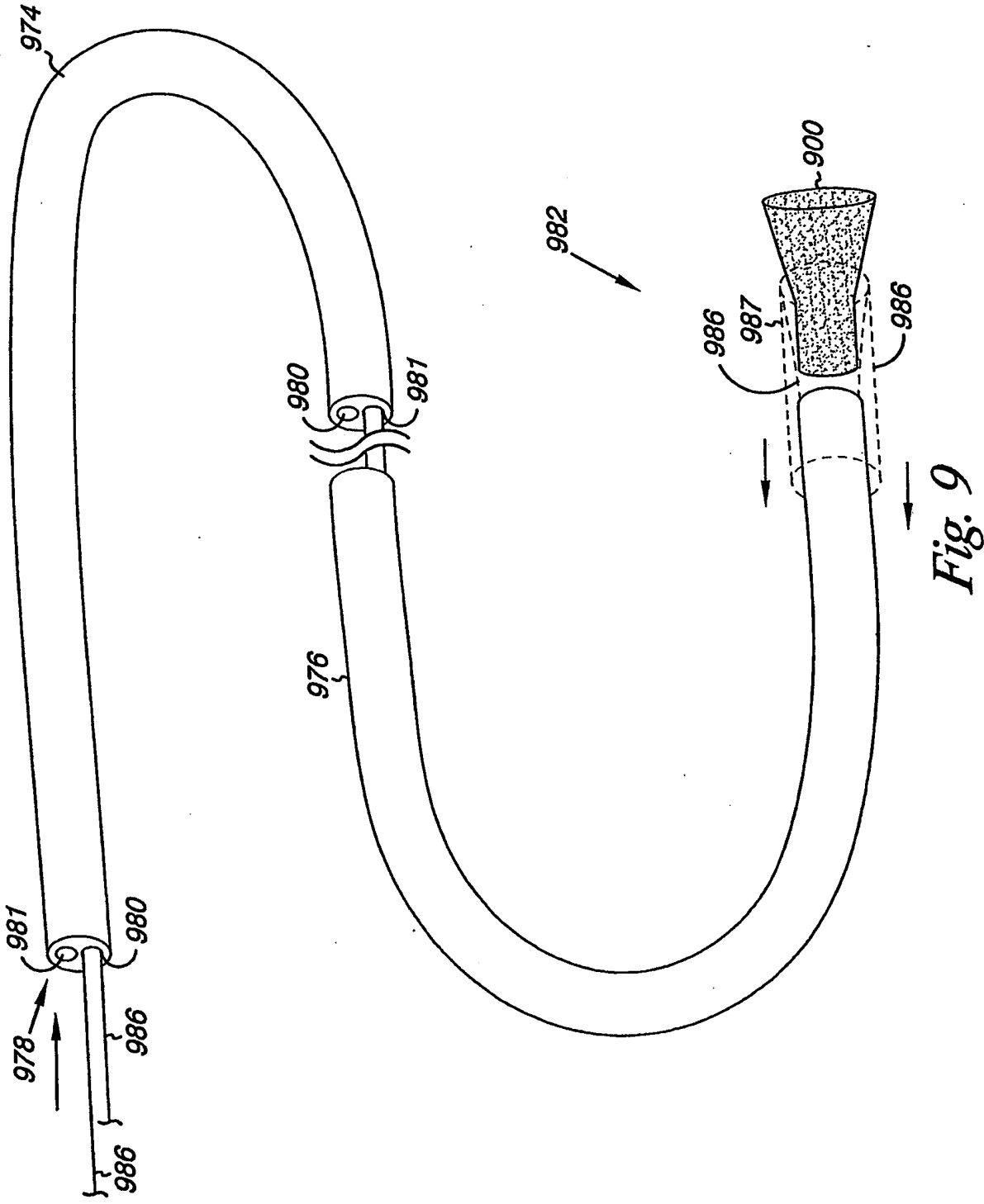


Fig. 7D





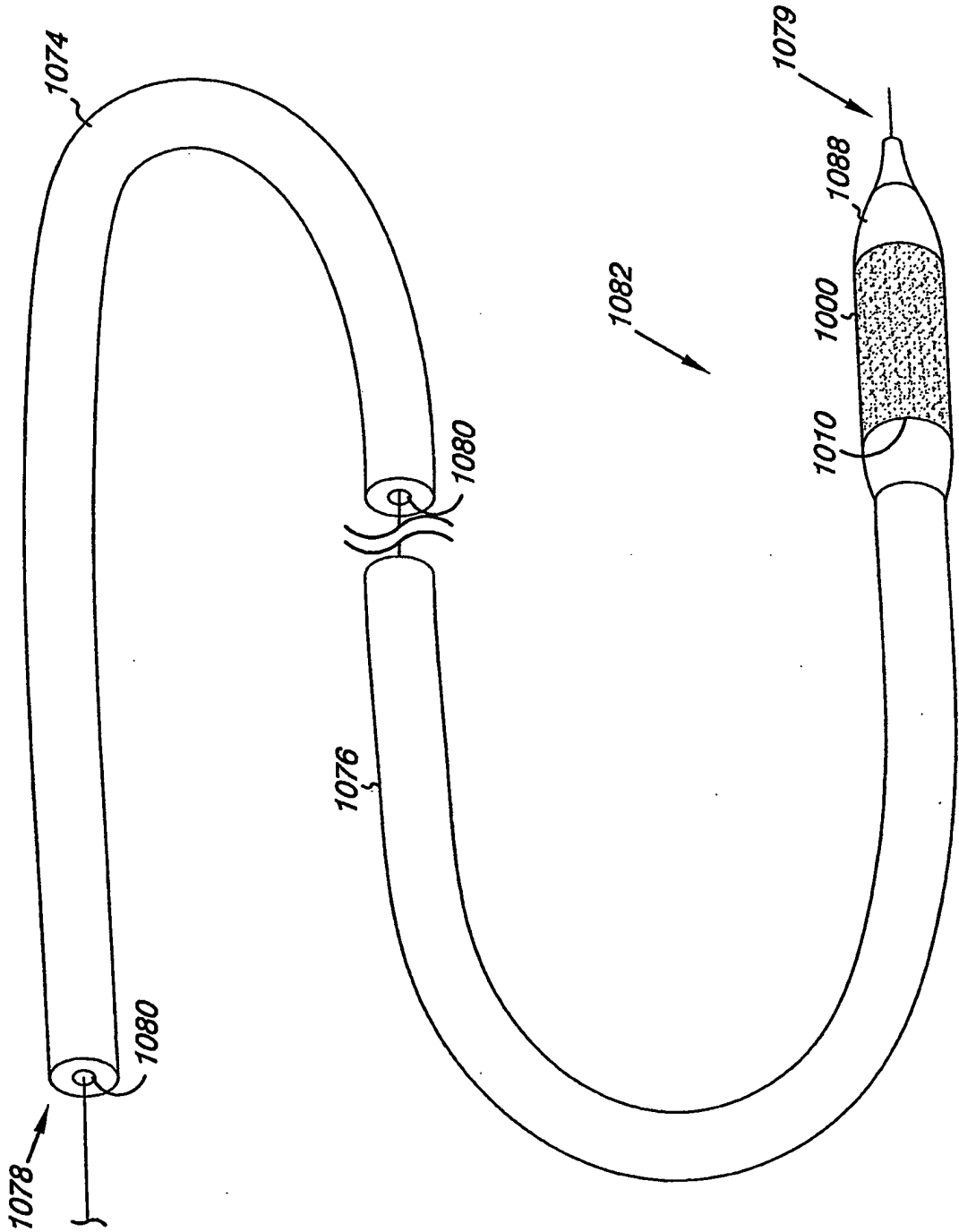


Fig. 10

INTERNATIONAL SEARCH REPORT

International Application No

PC1/US2004/042058

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/007956 A1 (LETAC BRICE ET AL) 12 July 2001 (2001-07-12) paragraphs '0087! - '0101!, '0140! - '0148!; figures 4,5,12,13	1,3, 10-19
X	US 5 469 868 A (REGER ET AL) 28 November 1995 (1995-11-28) the whole document	1-10,15, 16,20,21
X	US 4 477 930 A (TOTTEN ET AL) 23 October 1984 (1984-10-23) column 3, line 36 - column 7, line 25; figures	1-10,15, 16,20,21
X	US 3 755 823 A (HANCOCK W,US) 4 September 1973 (1973-09-04) column 2, line 63 - column 6, line 55; figures	1-10,15, 16,20,21
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☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

28 February 2005

Date of mailing of the international search report

11/03/2005

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/042058

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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